510(k) summary K022790

21 CFR 807.92

Date: 08/21/2002 AUG 2 8 2002

Official Contact: Winston Greer

Manufacturer: BioHorizons Implant Systems, Inc.
One Perimeter Park South
Suite 230 South
Birmingham, AL 35243
Phone: (205) 967-7880
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Proprietary Name

The AUTOTAC System™

Common Name

Membrane fixation pin

Classification Name

Screw, fixation, intraosseous

Predicate Device

The primary predicate device is The AUTOTAC System ™ consisting of bioresorbable membrane fixation pins, components and instruments manufactured and distributed by BioHorizons Implant Systems Inc. Authorization to legally market the predicate BioHorizons AUTOTAC System has been documented under the following 510(k) numbers: K993493, K011675

The predicate devices for the titanium tack are the IMZ Bone Tack System manufactured and distributed by INTERPORE Systems Inc. and IMTEC Bone Tac manufactured and distributed by IMTEC Corporation. Authorization to market the IMZ Bone Tack System has been documented under 510(k) numbers K952167. Authorization to market the IMTEC Bone Tac has been documented under 510(k) numbers K973180.

Device Description

The proposed membrane fixation tack is fabricated from titanium alloy as specified in ASTM F136 – Specification for Wrought Titanium 6AL-4V ELI Alloy for Surgical Implant Applications. This material was selected because of its known biocompatibility and mechanical properties. The tack is comprised of a low-profile, round, lens shaped head and a cylindrical shaft that is tapered to a point at its free end. The shaft is provided with a circular rib (barb) that aids in retention of the tack under normal loading conditions. Three opposing tabs extend from the head of each tack and are designed to secure the tack within the delivery mechanism while transporting to the surgical site. The tack is designed for implantation during the healing period during which tissue regeneration takes place. The tacks are provided non-sterile and are to be sterilized by the user using accepted steam sterilization techniques.

Device Description (cont'd)

The autoclavable tack holder is manufactured from ULTEM medical grade material and consists of 21 receptacles for the tacks. A rotating lid serves to capture the tacks during handling so that the tacks do not dislodge from the autoclavable tack holder. Titanium inserts serve to hold the tack so that the end of the tack does not create wear debris after continued use. The autoclavable tack holder can hold up to 21 tacks.

Intended Use

The AUTOTAC System™ is intended to fixate or stabilize bioresorbable barrier membranes used for regeneration of tissue and/or bone in the oral cavity or in other clinical situations that require membrane use/fixation.

Technological Characteristics

The Fundamental Scientific Technology of the modified device has not changed. The proposed AUTOTAC System fixation tack is substantially equivalent to all features of the predicate devices, which could affect safety or effectiveness due to the similarities in design and intended use.

Non Clinical Testing

Testing was conducted to validate that the metal tissue tack could be inserted into bone without pre-drilling the site and the tacks would not deform. Results showed the tack penetrated the bone analogs to a depth adequate enough to engage the tack barb. The tacks showed no structural deformation. Further in-vitro testing demonstrated that the membrane would tear before the tack could be dislodged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Mr. Winston Greer
Director, Quality Assurance & Regulatory Affairs
Biohorizons Implant Systems, Incorporated
One Perimeter Park South, Suite 230 South
Birmingham, Alabama 35243

Re: K022790
Trade/Device Name: The AutoTac System™ Titanium Tack
Regulation Number: 872.4880 and 880.3040
Regulation Name: Intrasseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: August 21, 2002
Received: August 22, 2002

Dear Mr. Greer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K022790

Device Name: The AutoTac System™ Titanium Tack

Indications for Use:

The AutoTac System™ Titanium Tack is intended to fixate and stabilize bioresorbable and non-resorbable barrier membranes used for regeneration of tissue in the oral cavity or in other clinical situations that require membrane use or fixation.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022790

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109)